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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,014

05/08/2006

Jesse J. Kuhns

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27777 7590 07/22/2008  
PHILIP S. JOHNSON  
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NEW BRUNSWICK, NJ 08933-7003

EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

PAPER NUMBER

3734

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,014	<b>Applicant(s)</b> KUHNS ET AL.	
	<b>Examiner</b> JENNIFER L. HORNBERGER	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 32, 33, 49 and 50 is/are rejected.
- 7) ☒ Claim(s) 8-31, 34-48 and 51-58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/08/2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Claim Objections***

1. Claim 1 is objected to because of the following informalities: "sais" in line 10 should be replaced with "said". Appropriate correction is required.
2. Claims 8-31, 34-48, and and 51-58 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1, 4/1, 5-7, 32/1, 33, and 49/1 are rejected under 35 U.S.C. 102(b) as being anticipated by Ewerhardt et al. (US 1,950,788).

Regarding claim 1, Ewerhardt et al. disclose a diagnostic device for pathologies of tubular anatomical structures comprising: a tubular elongated structure (10) developing between a proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure, means for locally dilating (12) the walls of the tubular anatomical structure being associated with the distal end of said elongated structure, said means for locally dilating being movable between a closed position (Fig. 1) for the introduction of the device and at least one open position (Fig. 2) for the viewing and evaluation of the pathology, control means (21) being associated to the proximal end of the elongated structure, said control means being operatively connected to said means

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for locally dilating in order to move them between the closed position and the open position, and vice versa (col. 3, ln. 47-51).

Regarding claim 4, Ewerhardt et al. disclose the means for locally dilating comprise petals (12) being arranged such that one first end thereof is associated to the distal end of the elongated tubular structure, said petals being adapted to assume at least one closed configuration (Fig. 1) and one open configuration (Fig. 2).

Regarding claim 5, Ewerhardt et al. disclose a petal comprises an arm which broadens into a curved surface (Fig. 2).

Regarding claim 6, Ewerhardt et al. disclose said curved surface has an asymmetric conformation with respect to the respective arm (Fig. 1).

Regarding claim 7, Ewerhardt et al. disclose said curved surface comprises a side extension suitable to overlap to the adjacent petal at least in the closed configuration of the petals (Fig. 1).

Regarding claim 32, Ewerhardt et al. disclose means for dilating comprise arms being arranged such that a first end thereof is associated with the distal end of the elongated tubular structure, said arms being suitable to assume at least one closed configuration (Fig. 1) and one open configuration (Fig. 2).

Regarding claim 33, Ewerhardt et al. disclose at least one arm comprises a straight length suitable to be fixed to the elongated structure and a curved length (Fig. 2).

Regarding claim 49, Ewerhardt et al. disclose said elongated structure comprises an inner tube and an outer tube adapted to internally receive said inner tube, said inner tube and said outer tube being adapted to translated relative to each other in order to open and close said means for locally dilating the walls (col. 3, ln. 15-19).

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2, 3, 4/2, 4/3, 5-7, 32/2, 32/3, 33, 49/2, 49/3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) in view of Sinnreich (US 3,882,852).

Regarding claim 2, Ewerhardt et al. disclose the claimed invention as discussed above except for a means of viewing adapted to be associated with the elongated tubular structure and reach the tract of the tubular anatomical structure dilated by the means of dilating. Sinnreich discloses an endoscope associated with a cervical dilator permits visualization of the treatment area during examination as well as biopsy and cauterizing procedures (col. 1, ln. 7-19, col. 3, ln. 8-14). Therefore, it would have been obvious to combine an endoscope with the dilator of Ewerhardt et al. to allow one to view the surgical site as taught by Sinnreich.

Regarding claim 3, Ewerhardt et al. disclose the elongated tubular structure is internally hollow in order to receive the means of viewing.

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) as applied to claim 1 or over Ewerhardt et al. (US 1,950,788) and Sinnreich (US 3,882,852) as applied to claims 2 or 3 above, and further in view of Bertolero et al. (US 2005/0159645).

Regarding claim 50, Ewerhardt et al. disclose the claimed invention except for the outer surface of the outer tube comprises at least one detection element or marker. However, Bertolero et al. disclose a detection element or marker on an outer sheath

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(paragraph 8). It would have been obvious to provide a detection element or radiopaque marker on the outer tube to allow the location of the device in the body to be determined.

### ***Double Patenting***

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1-3 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of copending Application No. 11/662,032. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh  
07/17/08

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731